From: Abbie Divilio <AbbieD@Safechain.com>
Sent: Tue 10/13/2020 7:30:02 PM (UTC)
To: Charles Boyd <CharlesB@Safechain.com>
Cc: compliance <compliance@Safechain.com>
Subject: FDA FORM 3911
Attachment: FDA 3911 BIKTARVY.pdf

Charlie,
I have completed the FDA 3911 form. I have classified the even as 'fraudulent information' since Gilead is unable to verify the transaction. It seems that the purpose of the form is for information gathering maybe if this drug and lot number are reported in an adverse reaction claim. Once the form is submitted, the FDA assigns the form a reference number. From there, I suppose the FDA will look into the matter further to determine if they need more information.

Please let me know how you would like to proceed. I have attached the completed form for you to review.

Thanks,

Abbie Divilio | Director of Compliance
Safe Chain Solutions, LLC
822 Chesapeake Drive | Cambridge, MD 21613
office: 855.437.5727 x1017 | fax: 866.930.1128
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. 0910-0806
Expiration Date: January 31, 2022
See PRA Statement on page 2.

Refer to instruction sheet (Form FDA 3911 Supplement) for more information.

1. Type of Report *(Select one)*: ☒ Initial Notification ☐ Follow-Up Notification ☐ Request for Termination

2. Incident Number *(Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)*

3. Date of Initial Notification to FDA *(mm/dd/yyyy)*	4. Date Company Determined Product Was Illegitimate *(mm/dd/yyyy)*	5. Classification of Notification *(Select from list)*
10/13/2020	10/09/2020	Fraudulent Transaction

Description of Product

6. Name of Product as It Appears on Label
BIKTARY 30CT

7. Primary Ingredients(s) *(if known)*
BICTEGRAVIR, EMTRICITABIN, TENOFOVIR ALAFENEMIDE FUMARATE

8. Drug Use *(Select from list)*	9. Drug Description *(Select from list)*
Human Use	Finished Prescription Drug

10. Strength of Drug	11. Dosage Form *(Select from list)*
50MG/200MG/25MG	Tablet

12. Quantity of Drug *(Number and Unit)*	13. NDC Number *(if applicable)*	14. Serial Number *(if applicable)*
1	61958-2501-01	

15. Lot Number(s)
CDGXKA

16. Expiration Date(s)

17. For Notification: Description of Event/Issue

Safe Chain was attempting to verify the T3 for this drug. We reached out to the manufacturer, Gilead, and they informed us that they were unable to verify the transaction of sale to the authorized distributor listed on the T3.

Add Page for Item 17

18. For Request for Termination of Notification: Description of why notification is no longer necessary

Add Page for Item 18

19. If you have submitted information to FDA through an alternative mechanism, check all that apply.

☐ BPDR ☐ MedWatch 3500 ☒ None
☐ FAR ☐ MedWatch 3500A ☐ Other *(Specify)*: _____

Company/Facility Information

20. Company Name & Address

Name
Safe Chain Solutions

Address 1 *(Street address, P.O. box, etc.)*
822 Chesapeake Drive

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City	State/Province/Region	ZIP or Postal Code
Cambridge	MD	21601

Country
United States

21. Company Category *(Select from list)*

Wholesale Distributor

22. Unique Facility Identifier *(of company named in #20)*

02566729

23. Contact Information *(Note: For the telephone, you may enter the number of either the contact person or of the company named in #20.)*

Name	Telephone Number *(Include area code)*
Abigail Divilio	855-437-5727

Email Address
compliance@safechain.com

SUBMIT BY EMAIL

A willfully false statement is a criminal offense, pursuant to U.S. Code, title 18, section 1001.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."